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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,298	06/27/2003	Paola LaColla	IDX 1017 US 06171.105078	9201

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EXAMINER	
MCINTOSH III, TRAVISS C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/609,298	LACOLLA ET AL.	
	Examiner	Art Unit	
	Traviss C. McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Due to the complexity of the instant restriction requirement, the examiner has broken the claims up into the following groups, each of which may, and most likely will, be further restricted into additional groups in a subsequent restriction. Moreover, it is noted that the claims of the instant application encompass hundreds of independent and distinct inventions. For example, claim 1 of the instant application is drawn to compounds which are identical to those of application 11/005,471, which was restricted into 4 groups. Claim 2 of the instant application is drawn to compounds which are identical to those of application 11/005,442, which was restricted into 4 groups, and so on.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 26-32, and 37-42, drawn to compounds and of claim 1, classified in class 536, subclass 26.1+.

II. Claims 2, 26-32, and 37-42, drawn to compounds of claim 2, classified in class 536, subclass 26.1+.

III. Claims 3, 26-32, and 37-42, drawn to compounds of claim 3, classified in class 536, subclass 26.1+.

IV. Claims 4, 26-32, and 37-42, drawn to compounds of claim 4, classified in class 536, subclass 26.1+.

V. Claims 5, 26-32, and 37-42, drawn to compounds of claim 5, classified in class 536, subclass 26.1+.

VI. Claims 6, 26-32, and 37-42, drawn to compounds of claim 6, classified in class 536, subclass 26.1+.

VII. Claims 7, 26-32, and 37-42, drawn to compounds of claim 7, classified in class 536, subclass 26.1+.

VIII. Claims 8, 26-32, and 37-42, drawn to compounds of claim 8, classified in class 536, subclass 26.1+.

IX. Claims 9-11, 26-32, and 37-42, drawn to compounds of claim 9, classified in class 536, subclass 26.1+.

X. Claims 10, 26-32, and 37-42, drawn to compounds of claim 10, classified in class 536, subclass 22.1+.

XI-XX. Claims 11-12, 17-25, drawn to methods of treating a host infected with a *Flaviviridae* infection by administering a compound from groups I-IX, classified in class 512, various subclasses.

XXI-XXX. Claims 13-16, drawn to methods of treating a host infected with a *Flaviviridae* infection by administering a compound from groups I-IX and an additional antiviral agent, classified in class 514, various subclasses.

XXXI-XXXX. Claims 33-36, drawn to compositions comprising the compounds of groups I-IX and an additional antiviral agent, classified in class 514, various subclasses.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-X are drawn to patentably distinct compounds. The examiner would like to note that chemical structures which are similar are presumed to function similarly, while chemical structures which are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of ***Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)***, and ***In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984)***, chemical structures are patentably distinct where structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

It is noted that each of the above compound groups may be subject to further restrictions.

Inventions I-X and XI-XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of using the product as claimed can be practiced with another materially different product, such as with any of the other products of Groups I-X, or with the compounds of Beaulieu et al. for example (US Patent 6,479,508).

Inventions I-X and XXI-XXX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for

using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of using the product as claimed can be practiced with another materially different product, such as with a composition not comprising an additional anti-viral agent, or with the compounds of Beaulieu et al. (US Patent 6,479,508).

Inventions I-X and XXXI-XXXX are patentably distinct. The compositions of Groups XXXI-XXXX require the compound of Group I-X and a second anti-viral agent. It is noted that a reference disclosing a compound of Group I-X would not necessarily disclose compositions comprising multiple agents as set forth in Groups XXXI-XXXX. As such, the compositions of Groups XXXI-XXXX would require further search and examination to determine patentability.

Inventions XI-XX and XXI-XXX are patentably distinct. The methods of Group XXI-XXX require the compound of Group I-X and a second anti-viral agent. It is noted that a reference disclosing a method of treatment as set forth in Group XI-XX would not necessarily disclose methods using multiple agents as set forth in the methods of Groups XXI-XXX. As such, the methods of treatment set forth by Group XIX-XXX would require further search and examination to determine patentability.

Inventions XI-XX and XXXI-XXXX are patentably distinct. The methods of Group XI-XX only requires the compound of Group I-X while the composition of Group XXXI-XXXX requires the compound of Group I-X and another anti-viral agent. It is noted that a reference disclosing a method of treatment as set forth in Group XI-XX would not necessarily disclose compositions comprising multiple agents as set forth in the compositions of Group XXXI-

XXXX. As such, the compositions set forth by Group XXXI-XXXX would require further search and examination to determine patentability.

Inventions XXI-XXX and XXXI-XXXX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of using the product as claimed can be practiced with another materially different product, such as with the product of Group I-X, or with the compounds of Beaulieu et al. (US Patent 6,479,508).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one Group is not required for another Group, restriction for examination purposes as indicated is proper.

Claims 1-42 are generic to a plurality of disclosed patentably distinct species comprising a plethora of divergent compounds represented by the Markush groups for the compounds of claim 1. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. By a single species it is meant a single compound. The compound may be named in any of four ways: 1) according to IUPAC standard, 2) by a pictorial representation of the compound, 3) by setting forth the specific chemical group that each variable of the Markush group represents, or 4) by naming a claim or an example which itself sets forth a

single compound. If applicants elect a group which comprises multiple agents (any of groups XXI-XXXX), applicants are also required to elect a single "additional agent" which is intended to be used in the method/composition. The single "additional agent" should be named in a way to clearly distinguish that which the agent is.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Due to the complexity of the instant restriction requirement, no telephone call was made to applicants to request an oral election to the above restriction requirement.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
December 28, 2005

James O. Wilson
Supervisory Patent Examiner
Art Unit 1624